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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,380	01/04/2002	Thadeu Rezende Provenza	71370-0001	3774

7590 05/21/2003

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Washington, DC 20036-3506

EXAMINER

SAADAT, CAMERON

ART UNIT	PAPER NUMBER
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3713

DATE MAILED: 05/21/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,380

Applicant(s)

PROVENZA, THADEU REZENDE

Examiner

Cameron Saadat

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. It appears that the instant application is a direct translation into English from a foreign document. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The specification does not describe reference "7a,b,c" presented in Figure 3 of the Drawings. Correction is required.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "5B" has been used to designate two elements in Figs. 3 and 4. Furthermore, the Figures fail to show references "5d", "5f", "A1", "A2", and "A3" as described in the specification on page 3. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 4,867,686).**

Regarding claim 1, Goldstein discloses a device for simulating a human mammary gland for training in the detection of pathological occurrences by palpation, wherein the device comprises: a base 14, supporting stuffing material 18 to simulate the inside tissue of a mammary gland having a texture simulating the existence of pathologies. Goldstein does not explicitly disclose that the base is rigid. However, it is the examiner's position that providing a rigid base for a breast model is notoriously old and well known for supporting the breast model, and at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the base of Goldstein by providing a rigid base to further support the breast model.

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Regarding claim 2, Goldstein discloses a device for simulating a human mammary gland, wherein the simulated pathologies are elements fixed in the base or in the stuffing material (Col. 5, lines 52-56), and wherein the elements are irregular or spherical (Col. 3, lines 40-45).

Regarding claim 3, Goldstein discloses a device for simulating a human mammary gland, comprising a pigmented areola and quadrants (Col. 6, lines 35-40; Col. 2, lines 49-51; Col. 4, line 41).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 4,867,686) in view of Barrie et al. (USPN 5,803,746).

Goldstein discloses a device for simulating a human mammary gland, wherein the pathology elements are pigmented to represent various secretion types (Col. 4, lines 44-47). It is not explicitly disclosed that the secretions are *emerged* after being applied with pressure. However, Barrie discloses a device for simulating a mammary gland, wherein secretion may be discharged with the pressure of a syringe. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the breast model described in Goldstein, by allowing secretions to emerge after applying pressure, in light of the teachings of Barrie, in order to teach the clinical skill of breast cyst aspiration.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 4,867,686) in view of VanWinkle (USPN 5,913,686).

Goldstein discloses all of the claimed subject matter except for those directed towards providing a base comprising information of public interest and publicity. However, VanWinkle teaches a breast model wherein information of public interest is provided on the base. In view of VanWinkle, at the time of the invention, it would have been obvious to a person of ordinary skill

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in the art to modify the base described in Goldstein, by providing information of public interest, in order to provide informative and instructional information utilized in conjunction with the breast model and thereby enhancing training.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Cooper (WO 94/25948) – discloses a breast model comprising liquid.

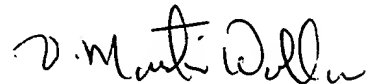
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Valencia Martin-Wallace can be reached on 703-308-4119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

CS

May 14, 2003



VALENCIA MARTIN-WALLACE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700